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10/750,409

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12/28/2009

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EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

NOTIFICATION DATE

DELIVERY MODE

12/28/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/750,409 | Applicant(s) MEULENBERG ET AL. | |
| | Examiner MYRON G. HILL | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,22,24-26 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,22,24-26 and 32-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/15/09 has been entered.

This action is on claims 21, 22, 24-26, and 32-37.

Claim Objections

Claim 21 was objected to because of the following informalities: there is an extra comma in line 4.

Applicant removed the comma and the objection is withdrawn.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 22, 24-26, 28, 30, and 32-37 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has amended the claims to require the PRRSV deposited under CNCM I-1102 which is shown in the specification to contain SEQ ID# 18 on the 5' end.

The rejection is withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 22, 24-26, 28, 30, and 32-37 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has amended the claims and the rejection is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 32 was rejected under 35 U.S.C. 102(a) as being anticipated by Calvert *et al.* (US 6500662).

The claims are drawn to SEQ ID# 24 or a sequence that hybridizes to SEQ ID# 24 under stringent conditions. The limitation of SEQ ID# 18 is discussed above.

Claim 32 was rejected under 35 U.S.C. 102(b) as being anticipated by Calvert *et al.* (EP 1018557 A2 pub 12-2000).

The claims are drawn to SEQ ID# 24 or a sequence that hybridizes to SEQ ID# 24 under stringent conditions. The limitation of SEQ ID# 18 is discussed above in the 102(a) rejection..

Applicant has amended the claims and the rejection is withdrawn.

Claim 32 was rejected under 35 U.S.C. 102(e) as being anticipated by Calvert *et al.* (US 6500662).

The claims are drawn to SEQ ID# 24 or a sequence that hybridizes to SEQ ID# 24 under stringent conditions.

Applicant has amended the claims and the rejection is withdrawn.

Rejections Maintained/ NEW

Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 32 requires a full length infectious clone that expresses a heterologous Orf7.

Paragraph 18 describes a chimera that consists of a replaced Orf7.

The examiner does not see support for the claim and requests applicant to point it out.

Claims 21, 22, 24- 26 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for the said claims. The specification does not provide a repeatable method for obtaining the specific deposits, and it does not appear to be readily available material. Deposit of the virus strain would satisfy the enablement requirements of 35 U.S.C. 112.

Applicant has removed the list of PRRSV strains but the PRRSV CNCM I-1102 strain is still recited.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that **all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent**, would satisfy the deposit requirements. See 37 CFR 1.808.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 21, 24, and 26 are rejected under 35 U.S.C. 102(b) as anticipated by Wensvoort *et al.* (WO 92/21375).

Applicant argues that product by process limitations serve as limitation citing Atlantic Thermoplastics and that the current claims recited making infectious clones while the cited art was not known to make them.

Applicant's arguments have been fully considered and not found persuasive.

It is not clear what part of the Atlantic Thermoplastics case applicant is referring too and the limitations it holds as different. It is noted that the courts discussion of product by process limitations includes *in re* Thorpe that says that identical products infringe. Applicant needs to point out how there product is different.

The Wensvoort *et al.* isolate is the same virus and the viral genome contained therein is an infectious RNA molecule. The genome of the virus of Wensvoort *et al.* is full length and thus contains SEQ ID# 18 at the genome end. The virus as the deposit CNCMI-1102 recited in the claims (see claim 1 of WO 92/21375).

Wensvoort *et al.* claim 4 describes a vector corresponding to the isolate deposit CNCMI-1102. This vector corresponds to the infectious agent, not the sequence disclosed in Wensvoort *et al.*

Wensvoort *et al.* isolated full length RNA for virus infections (page 27).

The term recombinant in claim 26 does not differentiate a recombinant virus from the viral isolate.

Applicants intended use limitations of infectious do not alter the fact that the claims are drawn to nuclic acid constructs, not methods of making infectious virus.

Thus, Wensvoort *et al.* anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21, 24-25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wensvoort *et al.* (WO 92/21375), Moormann *et al.* (Journal of Virology 1996, Vol 70, pages 763-770).

Applicant argues that prior art would not result in the invention because it does not teach SEQ ID# 18.

Applicant's arguments have been fully considered and not found persuasive.

Wensvoort *et al.* in claim 4 describes a vector corresponding to the isolate deposit CNCMI-1102. This vector corresponds to the infectious agent, not the sequence disclosed in Wensvoort *et al.*

Thus, the claims are unpatentable over Wensvoort *et al.* and Moormann *et al.*

Claims 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wensvoort *et al.* (WO 92/21375), and Moormann *et al.* (Journal of Virology 1996, Vol 70, pages 763-770) as applied to claims 21, 24-25, and 26, further in view of Drew *et al.*

Applicant does not address Drew *et al.* and does not say the arguments from the above rejection are meant for this rejection as well.

The rejection is maintained.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MYRON G. HILL whose telephone number is (571)272-0901. The examiner can normally be reached on M-Th and flex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

/M. G. H./
Examiner, Art Unit 1648